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Steven C. Shanks

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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/612,504
Filing Date: July 01, 2003
Appellant(s): SHANKS ET AL.

Sandra L. Etherton
For Appellant

EXAMINER'S ANSWER

This examiner's Answer supersedes the previous examiner's answer of November 1, 2007.

In view of petitions of June 29, 2007 and November 30, 2007, the briefs filed on June 29, 2007 and September 27, 2007 are moot.

This examiner's answer is in response to the appeal brief filed March 5, 2007 appealing from the Office action mailed September 28, 2006.

The rejection of claims 3-7, 16-22 and 23-29 as unpatentable over U.S. Patent 6,074,411 to Lai et al. in view of U.S. Patent 6,267,779 to Gerdes are withdrawn and the arguments by the Applicant regarding these are not addressed herein.

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The rejection of claims 30 and 32 as anticipated by U.S. Patent 6,074,411 to Lai et al. are withdrawn and the arguments by the Applicant regarding these are not addressed herein.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

No appeals or interferences are pending which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, however, a listing of copending patent applications or litigation related to the application on appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The general summary of claimed subject matter contained in the brief is correct, although characterization as a single laser is inaccurate as each embodiment has multiple laser sources.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: In the office action of September 28, 2006 only claims 1, 2, 8-10, 13-15 and 22 were rejected under 35 U.S.C. 102(b) as anticipated by Lai. The rejection of claims 30 and 32 as anticipated by U.S. Patent 6,074,411 to Lai et al. have

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been withdrawn. The rejection of claims 3-7, 16-22 and 23-29 as unpatentable over U.S. Patent 6,074,411 to Lai et al. in view of U.S. Patent 6,267,779 to Gerdes have been withdrawn. The obvious double patenting rejection was not restated in the office action of September 28, 2006. The Applicant holds that such rejection is not proper until the claims are found allowable, however, this is not supported by the MPEP. This will remain moot if the rejections under 35 U.S.C. 102 and 103 are affirmed.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,074,411	Lai	06-2000
6,267,779	Gerdes	07-2001
5,653,706	Zavislan et al.	08-1997
6,746,473	Shanks et al.	06-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 8-10, 13-15 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,074,411 to Lai et al. Lai et al. teach a multiple laser diode apparatus for therapy using multiple probes (Fig. 1), each with a laser diode (semiconductor diode) with a wavelength between 500 and 1500 nanometers operating at about 5 mW (Col. 2, lines 42-45) and the probe is disclosed as having focusing optics (Col. 2, lines 32-35). The wavelength range includes visible, red and infrared wavelengths. Lai teaches an embodiment with an adhesive (Fig. 1) and an embodiment with just a laser probe (Fig. 2). The second embodiment is clearly capable of being moved by an operator's hand while in operation with no other supporting structure. The control unit is interpreted as a base unit. The focusing optics

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are an optical arrangement and any optical element will result in some transformation of the beam as that is the reason for using such an element. The resultant beam will have some shape, although no specific shape is claimed.

Regarding claim 2, the destination of the beams is intended use with no limitation on the device structure.

Claims 1-10, 13-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,267,779 to Gerdes in view of U.S. Patent to Zavislan et al.

Gerdes discloses an apparatus for therapeutic laser treatment that includes handheld wands (Fig. 7) that each may deliver two wavelengths of laser energy, one in the near infrared range and the other in the visible range (Col. 8, line 54) from solid-state diode lasers (Col. 7, lines 22-24). The beams are combined and delivered to the wands that include adjustable optics to focus and shape the beams (Col. 8, lines 31-34). The beam shape may be circular or rectangular (Col. 9, line 49), or a variety of other patterns. This is interpreted as anticipating the various shapes claimed as a skilled artisan is capable of generating a desired shape and size of the beam and no specific benefit or unexpected result is disclosed for any of the claimed shapes. A controller for the sources is disclosed that may control the pulse parameters, including, continuous or pulsed, pulse duty cycle and duration of application for each of the radiation sources synchronously or independently with continuous operation possible by selection of a duty cycle of 100 percent (Col. 11, lines 3-8). Specifically mentioned is a pulse frequency of one hertz (Col. 11, line 63). The system is capable of emitting radiation at less than one watt; with 0 to 2.0 W specified for the infrared laser diode and 0 to 6 mW specified for the visible laser diode (Col. 9, lines 14 and 31). The wavelength disclosed for the visible beam is 400 to 700 nm (col. 9, line 38), and 900 to 1100 nanometers for the infrared beam (Col. 9, line

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27). It is noted that 400 nanometers is the limit of the ultraviolet spectrum (UV-A), thus teaching radiation in that spectrum. The handheld wands are connected to the radiation sources within the controller cabinet (base) via optical fibers (Col. 8, lines 23-25). Gerdes discloses a mode in which only the two aiming beams are generated (Col. 11, lines 45-50), after which, a routine is executed to determine if operation of the therapeutic laser is proper, thus teaching visible radiation only from the wands. Gerdes does not teach the laser sources within the wand or probe. Zavislan et al. teaches a hand held probe for delivery of laser energy to tissue. The laser beam may be provided by a laser source external to the housing which is introduced into the housing through an optical fiber cable or by a laser, such as a solid state laser (e.g. a laser diode) which is mounted in the housing. The housing contains optical means for projecting and focusing the beam (Col. 2, lines 62-67). Thus, Zavislan et al. teach the source may be located within or external to the probe and reinforces the use of optics with laser devices. It would have been obvious to one skilled in the art at the time the invention was made to mount the laser source within the probe as taught by Zavislan et al. in the invention of Gerdes to eliminate the need for an optical fiber, make the device portable and better control the beam path. Zavislan et al. suggests this mounting and advances in laser technology have reduced the size of laser sources further enabling internal mounting. Note that Lai et al., as discussed above, also teaches internal mounting of laser diodes in a probe, providing another teaching of mounting a laser source within a probe or handpiece.

Regarding claim 30, Gerdes teaches the probes radiate in the visible range of 400 to 700 nanometers, yet does not specifically disclose the radiation of the probes at different visible wavelengths. One of skill in the art would recognize the need to be able to differentiate the beams from each probe and would therefore provide a means to do so. An obvious means for differentiation would be a different color beam.

(10) Response to Arguments

The Applicant argues that Lai et al. fails to disclose moving the laser probes while emitting laser beams. An apparatus claim is based on the structure of the device without regard to the manner in which it is intended or might be used. Lai et al. clearly anticipates the structure of the claimed device. Further, Lai et al. teach a specific embodiment without an adhesive ring (Fig. 2) that is clearly capable of being freely moved by a hand while radiating. Lai et al. therefore, does not teach away from moving the wand by hand.

Lai et al. clearly teach the use of optics as laser diodes inherently include at least a protective lens. The beam inherently must have some shape. The claims rejected by Lai et al. only specify a shape with no specific shape claimed.

Applicant's arguments regarding rejection of claims 30 and 32 by Lai et al. are in error as these claims are no longer in the Lai et al. rejection.

A skilled artisan includes both the laser and optics arts as the two are used together extensively as evidenced by the cited references.

The obvious double patenting rejections will be held in abeyance pending the appeal. Such rejections are not dependent on the claims having been allowed as stated by the Applicant.

The examiner takes the position that Zavislan et al. is clearly analogous art in that it is a device for irradiating tissue with a laser beam. Such laser radiation is classified in class 606 or class 607 depending of whether the treatment is surgical (cutting, coagulating, etc.) or therapeutic (tanning, photodynamic, etc). The determining factor is usually the laser intensity, with the structures being very similar, thus they are analogous art. The issue is moot in that Zavislan et al. is used as a teaching for mounting a laser within a probe, a structural feature that

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may as likely be found in a wood or metal etching probe as well as a medical device. KSR clearly teaches such as transferable between arts.

Regarding Zavislan et al. teaching away from using multiple probes, as stated above, Zavislan et al. is used for an entirely different rationale, that of mounting the energy source within the probe or handpiece. The evolution of technology to smaller laser sources has enabled the mounting in smaller enclosures.

Arguments regarding movement of the probes of Gerdes and Zavislan et al. are related to the use of the device. The structures of both Gerdes and Zavislan et al. are capable of being moved while radiating. It is noted for the record that devices with interlocks to prohibit radiation unless in contact with skin are known. Neither Gerdes nor Zavislan et al. disclose such an interlock.

Regarding radiation simultaneously on different parts of a body, Gerdes clearly teaches simultaneous operation and is capable of directing the probes to different tissue areas. As previously discussed, Zavislan et al. provides a teaching of mounting a source within a probe. This limited teaching does not impact the intended use of the device.

Regarding the argument that the combination of Gerdes and Zavislan et al. does not teach UV radiation, Gerdes explicitly discloses a wavelength preferably between approximately 400 nanometers to approximately 700 nanometers (Col. 9, line 38), the 400 nanometers is both visible and at the high end of the UV-A spectrum.

Regarding the shape of the treatment spot, Gerdes clearly teaches a variety of spot shapes; i.e. "although a circular beam shape of approximately 4 mm is disclosed, a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention. Such patterns also include rectangular, square, oval, and elliptical patterns, as well as predetermined or random movably scanned or traced beam

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patterns that are adapted to be spread over a selected region or to trace a specific shape or pattern" (Col. 9, lines 45-53). One of skill in the art would clearly use such teachings to provide an irradiation spot appropriate for the intended target.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Henry M. Johnson, III/

Primary Examiner, Art Unit 3739

Conferees:

/Linda Dvorak/, Supervisory Patent Examiner

/Angela D Sykes/

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